REMARKS

Status of the Claims

Claims 1 and 3-9 are pending in the application. Claims 10-19 are new. Support for new Claims 10-19 can be found, for example, on page 2, lines 20-33.

All of the pending claims stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement and for lack of enablement. Claim 4 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claims 1, 4, and 6-9 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,163,896 to Suthanthiran ("Suthanthiran"). Claims 1, 3, 4 and 6-9 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Publication No. 2002/0054851 to Grunze ("Grunze"). Claims 1 and 3-9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over either one of Suthanthiran or Grunze in view of either one of U.S. Patent No. 6,152,869 to Park ("Park") or U.S. Patent No. 5,342,283 to Good ("Good"). Claims 1 and 4-9 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1 of U.S. Patent No. 6,547,816.

Each rejection is discussed below.

Double Patenting

Applicant submits that the enclosed terminal disclaimer overcomes the rejection of Claims 1 and 4-9 under the judicially created doctrine of obviousness-type double patenting over Claim 1 of U.S. Patent No. 6,547,816. Accordingly, Applicant requests that the double patenting rejection be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

Applicant traverses the rejection under § 112 for failing to comply with the written description requirement and for lack of enablement.

Written Description

The Action states that the limitation that "the nuclide is a chemically bound constituent of the polymer chain" is "not described in such as way as to reasonably convey to one skilled that the inventors had possession of such as claimed." As correctly noted in the Action, the specification describes the nuclide as preferably located in the "backbone" of the polymer on page 3, lines 23-24. The Action further states that being located in the backbone encompasses a different scope and provides a different meaning than the term "chain." The Action states that the backbone "includes pendent groups, while the chain is specifically limited to the chain of the polymer." The Action further cites U.S. Patent No. 5,873,811 to Wang ("Wang") as allegedly supporting that the "backbone" includes pendent groups, which are not part of the chain.

Applicant submits that the term "backbone" is well-understood in polymer chemistry to be defined by the principal chain in a polymer molecule. According to Polymer Chemistry: An Introduction Raymond B. Seymour and Charles E. Carraher, Jr., page 43 (3rd Edition; 1992), a "backbone" is defined as "the principal chain in a polymer molecule." A copy of the definition is attached as Exhibit A. Claim 1 has been amended to recite that "the nuclide is a chemically bound constituent of the backbone of a polymer." However, with reference to the definition provided in Exhibit A, Applicant submits that the terms "backbone" and "chain" are interchangeable and refer to the principal or main chain in a polymer molecule, *i.e.*, excluding side chains.

The Action further states that the specification fails to comply with the written description requirement because the various nuclides, such as I, F, etc. are not capable of being in the polymer chain, as these nuclides are monovalent. A nuclide that is a chemically bound constituent of the polymer chain or backbone is clearly described in the specification, for example, on page 3, lines 23-25 ("In generally, the nuclide is preferably located in the backbone of the polymer, although side chain configurations are possible."). As stated on page 3, lines 23-25, both side chain and polymer chain/backbone configurations are contemplated by the specification. Accordingly, the monomer elements recited in Claim 1 have been deleted, and new Claim 19 has been added, which recites that "the polymer further comprises a side chain comprising a second nuclide consisting of I, F or Cl."

Moreover, the Action states that the metals listed are only part of the chain in the poly(phenylmetallosiloxane) polymer. Applicant submits that metallopolymers are known to those of skill in the art and that, as noted in the Action, the specification includes one example of a metallopolymer. Examples of metallopolymers are given in *Metal-containing Polymeric Materials*, edited by C. U. Pittman, Jr. et al.; Plenum Press, New York, NY (1996) ("Pittman"), selected pages of which are attached as **Exhibit B**. According to Pittman:

> We have seen this field [inorganic and organometallic polymers] produce a wide variety of materials with diverse applications such as polymeric conductors and semiconductors, preceramic materials, polymer bound catalysts, shields for UV and other high energy radiation, biosensors, polymers with high thermal stability, flame retardency, and a wide variety of applications. Indeed, what can be expected when you incorporate the entire periodic table into a field that formerly had concentrated primarily on C, H, N, O, S, Si and the halogens? (emphasis added) (Pittman, page 3).

Pittman discusses numerous examples of metallopolymers known in the art. For example, metalloscene polymers are widely used in the aerospace industry (Pittman at 19). In a paper published in 1996, it was reported that the chemistry of metallosiloxane polymers has been studied for 25-30 years (Pittman at 229). According to the M.P.E.P. § 2163(II)(A)(3)(a), "[w]hat is conventional or well known to one of ordinary skill in the art need not be disclosed in detail." (citing *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986)). "If a skilled artisan would have understood the inventor to be in prossession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met." M.P.E.P. § 2163(II)(A)(3)(a) (citing *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991) and *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972)).

Accordingly, Applicant submits that the written description requirement has been satisfied and requests an indication of same.

Enablement

The Action further states that the specification "does not reasonably provide

enablement for the rest of the nuclides as set forth in claim 4, namely for I, F or Cl for any polymer and for any metal for any polymer other than poly(phenylmetallosiloxane).

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent application coupled with information known in the art without undue experimentation. MPEP §2164.01 (citing *In re Wands*, 858 F.2d 731, 737). As noted in the MPEP § 2164.04, the Examiner has the initial burden of establishing a reasonable basis to question the enablement provided for the claimed invention, and must explain why the truth or accuracy of any statement is doubted. "How a teaching is set forth, by specific example, or broad terminology, is not important." MPEP § 2164.08. The Patent Office has the affirmative burden to set forth evidence in support of the non-enablement rejection in order to establish even a *prima facie* case of non-enablement. MPEP § 2164.04; *In re Wright*, 999 F.2d 1557 (Fed. Cir. 1993); *In re Marzocchi* , 439 F.2d 220, 224 (CCPA 1971)).

As discussed above, the elements I, F and Cl have been deleted from Claim 1, and new Claim 19 has been added for clarification to recite that, in some embodiments, the polymer can further include "a side chain comprising a second nuclide consisting of I, F or Cl." Nuclides as part of the backbone of the polymer and side chain configurations are both discussed in the specification. See, *e.g.*, page 3, lines 23-25. Accordingly, Applicant submits that the specification is enabling for the nuclides I, F or Cl as recited in new Claim 19 and request that the rejection be withdrawn.

Regarding the position set forth in the Action that enablement is not provided "for any metal for any polymer other than poly(phenylmetallosiloxane)s, Applicant respectfully submits that the Action provides no objective, factual evidence to doubt the veracity of Applicant's specification, or to doubt that the invention works as described. Although the eight so-called "Wands factors" are set forth in the Office Action, the Action does not analyze Applicants' claims and disclosure in view of the eight factors in order to set forth any particular failings of the specification to enable the claims. The lack of enablement is thus merely alleged, but is not supported with any specific factual evidence.

Moreover, the specification provides substantial guidance and examples concerning various polymers that include activatable nuclides in the polymer chain or backbone as well

as techniques to activate such nuclides. For example, in discussing the relative skill of those in the art, the Action states that "there is no clear method [in the specification] of incorporating an atom into a polymer chain when the polymer chain does not contain such an atom." However, the specification provides numerous examples of known polymers that contain one or more of the nuclides described, for example, in Claim 4. Examples of these polymers are provided, for example, in Claim 3. Further examples of how to activate nuclides that are chemically bound constituents of a polymer backbone and/or side chain are provided. See, *e.g.*, page 3, lines 30-33 and page 8, lines 22-25.

For at least the foregoing reasons, Applicant respectfully submits that the rejection of the pending claims under 35 U.S.C. § 112, first paragraph, is improper and respectfully requests that this rejection be withdrawn.

Rejections under 35 U.S.C. §112, second paragraph

Applicant notes that "CI" is a typo and is meant to be "Cl" as noted by the Examiner. Claim 4 has been amended as described above. Accordingly, Applicant requests that the rejection under 35 U.S.C. §112, second paragraph, be withdrawn.

Prior Art Rejection under § 102

Claim 1, as amended, recites (emphasis added):

> An integral source material having at least one nuclide that is activated by exposure to radiation, the nuclide is a chemically bound constituent of the backbone of a polymer of the integral source material, wherein the integral source material is configured before activation to provide a device wherein the device is selected from the group consisting of test-objects, rectangular and disc shaped sources configured to radiate an area, radioactive enclosures, flood sources, nuclear imaging devices, shrouds and excitation sources for energy-dispersive fluorescence analysis.

As discussed above, the backbone of the polymer is the principal chain in a polymer molecule. In contrast, Suthanthiran clearly shows the radioactive nuclide as part of a pendant group. The polymer of Suthanthiran is reproduced below, in which ^{125}I is illustrated as part of

a pendant group and not as a chemically bound constituent of the backbone of the polymer as recited in Claim 1.

Moreover, Suthanthiran does not teach or suggest a nuclide that is activated by exposure to radiation nor does it teach an integral source material that is configured before activation to provide a device as recited in Claim 1. In some embodiments of the present invention, a non-radioactive nuclide is activated by exposure to radiation to form a radioactive nuclide. As a specific example, non-radioactive P^{31} that is a chemically bound constituent of the backbone of the polymer can be configured before activation to provide a device. The device can be subsequently bombarded with radiation, e.g., neutrons, to form a radioactive-phosphorus (P^{32}) based polymer from an inactive-phosphorus (P^{31}) based polymer. By fabricating the device prior to activation, exposure to radiation can be reduced and safety can be improved.

In contrast, Suthanthiran discusses a radioactive-absorbing coating material in a binder material. See col. 2, lines 64-66. The nuclides in Suthanthiran are radioactive isotopes used to label a polymer. See col. 3, lines 16-24 ("an aromatic polyamino acid such as polytyronsine (which is commercially available in powder form) can be labeled with ^{125}I at the 3' and 4' positions of the aromatic ring of the tyrosine molecules of the polypeptide chain."). Unlike embodiments of the present invention, using the radioactive isotopes described in Suthanthiran during the manufacturing process may be hazardous.

Similarly, Grunze proposed radioactively labeled polymers that are prepared using radioactive isotopes. For example, Grunze discusses condensing ^{32}P-labeled phosphorus pentachloride, which is radioactive, with ammonium chloride. See paragraph 37. The resulting radiolabeled hexachlorocyclotriphosphazene is polymerized, resulting in radiolabeled polydichlorophosphazene, which is then esterified. See paragraph 38. Accordingly, Grunze describes "hot chemistry" methods, which require using radioactive isotopes during a manufacturing process. Moreover, the radiolabeled antithrombogenic polymer in Grunze is applied as a coating on the surface of a substrate. See paragraph 24. The coating can have a thickness of about 1 nm up to about about 1 μm. See paragraph 25.

Accordingly, neither Grunze nor Suthanthiran teach or suggest a nuclide that is activated by exposure to radiation or an integral source material that is configured before

activation to provide a device as recited in Claim 1. For at least the foregoing reasons, Applicant respectfully submits that the rejection of the pending claims under 35 U.S.C. § 102 is improper and respectfully requests that this rejection be withdrawn.

Prior Art Rejections Under § 103

With respect to the Claim rejections under 35 U.S.C. § 103(a), the Action states that Park discloses that the nuclide can be one that is activatable by irradiation and that "[i]t would have been obvious to one of ordinary skill in the art to use a nuclide which is activatable in the radioactive polymer based radioactive source disclosed by Suthanthiran or Grunze because it is well known in the art that the use of a radioactivatable nuclide (*e.g.*, a radionuclide precursor) may be used in a radioactive source as equivalent to radionuclides for easier and safer preparation."

Park proposes a radionuclide that is evenly mixed with a carrier material and dried to be dispersed and fixed within the carrier polymer. See col. 6, lines 24-29. That is, the carrier material is dispersed or mechanically incorporated within the carrier polymer. Park then discusses a "post-irradiation method." According to Park, a sleeve which contains stable isotopes can be adhered onto a non-radioactive stent and then irradiated with neutrons in a nuclear reactor. Park describes problems associated with post-irradiation including undesirable radioactive rays emitted by the metallic stent. See col. 6, lines 30-50. Good merely states generally "[i]t is a still further object of the invention to provide a novel method for incorporation of a nonradioactive elemental isotope into a seed during manufacture of a seed that will later form the desired radioactive isotope when the finished seed is bombarded with neutrons." Nothing in Park or Good suggests that post-irradiation could be successful to irradiate a nuclide that is a chemically bound constituent of the backbone of a polymer.

Applicant respectfully submits that the rejection of the pending claims under 35 U.S.C. § 103(a) is improper and respectfully requests that this rejection be withdrawn.

New Claims 10-18 are patentable

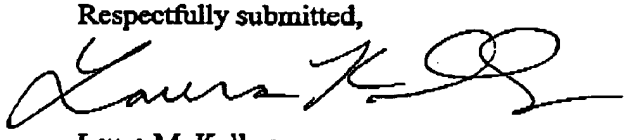
New Claims 10 recites a method of forming an integral source material comprising: providing an integral source material comprising a polymer chain having at least one nuclide

that is activated by exposure to radiation and a chemically bound constituent of the backbone of the polymer of the integral source material; forming the integral source material into a device, wherein the device is selected from the group consisting of test-objects, rectangular and disc shaped sources configured to radiate an area, radioactive enclosures, flood sources, nuclear imaging devices, shrouds and excitation sources for energy-dispersive fluorescence analysis; and exposing the integral source material to radiation to activate the at least one nuclide of the polymer chain. Applicant submits that these steps are not disclosed in any of the cited prior art. Accordingly, Applicant submits that new Claim 10 and 11-18 depending therefrom are allowable and requests an indication of same.

Conclusion

In light of the above amendments and remarks, Applicants respectfully submit that the application is in condition for allowance and respectfully requests same. The Examiner is requested to contact the undersigned to resolve any remaining issues.

Respectfully submitted,



Laura M. Kelley
Registration No. 48,441

Myers Bigel Sibley & Sajovec
P.O. Box 37428
Raleigh, NC 27627
(919) 854-1400 phone
(919) 854-1401 fax

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being sent by facsimile transmission to the United States Patent and Trademark Office, Group Art Unit 1616 at (703) 872-9306 on September 30, 2003.

Laura M. Kelley
Date of Signature: September 30, 2003
330626